[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day comment request

The Framingham Heart Study (NHLBI).

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on 12/31/2015, pages 81830-81832. No comment s were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. Deshiree Belis, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Dr., Suite 6185A, Bethesda, MD 20892, or call non-toll-free number 301-435-1032, or E-mail your request, including your address to deshiree.belis@nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: The Framingham Heart Study, 0925-0216, Revision, National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH).

Need and Use of Information Collection: This proposal is to extend the Framingham Study to examine the Generation Three Cohort, New Offspring Spouses and Omni Group 2 Cohort, as well as to continue to monitor the morbidity and mortality which occurs in all Framingham Cohorts. The contractor, with the collaborative assistance of NHLBI Intramural staff, will invite study participants, schedule appointments, administer examinations and testing, enter information into computer databases for editing, and

prepare scientific reports of the information for publication in appropriate scientific journals. All participants have been examined previously and thus the study deals with a stable, carefully described group. Data are collected in the form of an observational health examination involving such components as blood pressure measurements, venipuncture, electrocardiography and a health interview, including questions about lifestyles and daily living situations. The National Heart, Lung, and Blood Institute uses the results of the Framingham Study to: 1) characterize risk factors for cardiovascular and lung diseases so that national prevention programs can be designed and implemented; 2) evaluate trends in cardiovascular diseases and risk factors over time to measure the impact of overall preventive measures; and 3) understand the etiology of cardiovascular and lung diseases so that effective treatment and preventive modalities can be developed and tested. Most of the reports of study results have been published in peer reviewed medical journals and books.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 8,382.

Estimated Annualized Burden Hours

Table A.12-1.1
ESTIMATE OF RESPONDENT BURDEN, ORIGINAL COHORT
ANNUALIZED

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Time per Response (in hours)	Total Annual Burden Hour
I. PARTICIPANT COMPONENTS				
ANNUAL FOLLOW-UP				
a. Records Request (Attach #5)	30	1	15/60	8
b. Health Status Update (Attach #3)	30	1	15/60	8
SUB-TOTAL:PARTICIPANT COMPONENTS	30*	----------	----------	15
II. NON- PARTICIPANT COMPONENTS				
A. Informant Contact (Pre-exam and Annual Follow-up) (Attach #3-pages 3-7)	15	1	10/60	3
B. Health Care Provider Records Request (Annual follow-up) (Attach #5)	30	1	15/60	8
SUB-TOTAL:NON-PARTICIPANT COMPONENTS	45	----------	----------	10
TOTAL: PARTICIPANT AND NON-PARTICIPANT COMPONENTS	75	75		25

*** Number of participants as reflected in Row I.b. above**

Table A.12-1.2
ESTIMATE OF RESPONDENT BURDEN, OFFSPRING COHORT and OMNI GROUP 1 COHORT
ANNUALIZED

Type of Respondent	Number of	Number of	Average Time	Total Annual

	Respondents	Responses per Respondent	per Response (in hours)	Burden Hour
I. PARTICIPANT COMPONENTS				
ANNUAL FOLLOW-UP				
a. Records Request (Attach #5)	1500	1	15/60	375
b. Health Status Update (Attach #3)	1700	1	15/60	425
SUB-TOTAL: PARTICIPANT COMPONENTS	1700*	----------	----------	800
II. NON- PARTICIPANT COMPONENTS				
A. Informant contact (Pre-exam and Annual Follow-up) (Attach #3-pages 3-7)	150	1	10/60	25
B. Health Care Provider Records Request (Annual follow-up) (Attach #5)	1500	1	15/60	375
SUB-TOTAL:NON-PARTICIPANT COMPONENTS	1650	----------	----------	400
TOTAL: PARTICIPANT AND NON-PARTICIPANT COMPONENTS	3350	3350		1200

*** Number of participants as reflected in Row I.b. above**

Table A.12-1.3
ESTIMATE OF RESPONDENT BURDEN, GENERATION 3 COHORT, NOS and OMNI GROUP 2 COHORT
ANNUALIZED

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Time per Response (hours per year)	Total Annual Burden Hour
I. PARTICIPANT COMPONENTS				
A. PRE-EXAM				
1.Telephone contact for appointment	1,450	1	10/60	242
2. Exam appointment, scheduling, reminder and instructions **(Attach #6)**	1,270	1	35/60	741
B. EXAM CYCLE 3				
1. Exam at study center **(Attach #1)**	1,200	1	90/60	1,800
2. Consent **(Attach #10)**	1,200	1	20/60	400
2. Home or nursing home visit **(Attach #1 – partial as respondent is capable)**	35	1	1	35
C. **POST-EXAM** eFHS Mobile Technology for Collection of CVD Risks **(Attach #2)**	1,100	18	9/60	2,970
D. ANNUAL FOLLOW-UP				
1. Records Request **(Attach #5)**	1,200	1	15/60	300
2. Health Status Update **(Attach #3)**	1,400	1	15/60	350
SUB-TOTAL: PARTICIPANT COMPONENTS	**2,850***	**----------**	**----------**	**6,830**
II. NON- PARTICIPANT COMPONENTS – ANNUAL FOLLOW-UP				
A. INFORMANT CONTACTS (Attach #3 – pages 3-7)	180	1	10/60	30
B. Health Care Provider RECORD REQUEST (Attach #5)	1,155	1	15/60	289
SUB-TOTAL:NON-PARTICIPANT COMPONENTS	1,335	----------	----------	319
TOTAL: PARTICIPANT AND NON-PARTICIPANT COMPONENTS	4,185	28,890		7,157

*** Number of participants as reflected in Rows I.A.1 and I.D.2 above**

Estimates of annualized total hour burden are summarized in Table A.12 – 1.4 below.

Type of Respondent	Number of Respondents	Number of Responses Per Respondent	Average Time per Response (in hours)	Total Annual Burden Hour
Participants	4580	1	90/60	7,653
Non-Participants	3030	1	15/60	729
Totals	7610	2		8,382

(Note: reported and calculated numbers differ slightly due to rounding.)

Dated: April 4, 2016

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Valery Gheen

NHLBI Project Clearance Liaison

National Institutes of Health

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